

**REMARKS/ARGUMENTS**

This is in response to the Final Office Action dated Nov. 17th, 2006 and Advisory Action dated March 13<sup>th</sup>, 2007.

No claims are amended, no claims are cancelled, and no claims are added; as a result, claims 1-4, 6, and 9-10 are now pending in this application.

The 35 U.S.C. §103 Rejection

Claims 1-4, 6, and 9-10 are rejected under U.S.C 103(a) as being unpatentable over Ebert, et. al (U.S. 2003/0147926) in view of Ikeda, et al. (U.S. 6,207,184).

Applicant traverses the rejection and submits that *prima facie* obviousness has not been established. Applicant submits that the proposed combination of Ebert and Ikeda does not teach or fairly suggest the elements recited in the claims.

As explained previously, the use of appropriate alkaline agent is critical in producing a homogeneous and stable gel formulation of oxybutynin. The present invention teaches the use of diisopropanolamine, an unique alkaline agent in oxybutynin gel formulation. Applicant is unable to find a teaching or disclosure of using diisopropanolamine as pH adjuster in gel formulation in the proposed combination of cited references. Applicant notes that the cited Iketa patent discloses a hydrophilic plaster which points to a very different composition from elements recited in the instant application. Thus, they are not properly combinable in the manner proposed. For instance, Ikeda et al. teach a hydrophilic adhesive mass (hydrolytic plaster) that contains a copolymer of an aminoalkyl (meth)acrylate and an alkyl (meth)acrylate. Iketa et al. further disclose that the hydrophilic adhesive mass can be optionally incorporated with various additives, such as diisopropanolamine. In contrast, the claimed subject matter refers to the use of the diisopropanolamine as pH adjuster in the topical gel formulation of oxybutynin, not to the use of a hydrolytic plaster. The asserted motivation concerning the proposed combination of Ebert and Ikeda is improper.

To establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge

generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference must teach or suggest all the claim limitations. MPEP § 2143. *See also, In re Rouffet*, 47 USPQ2d 1453 (Fed. Cir. 1998). The court in *Rouffet* stated that "even when the level of skill in the art is high, the Board must identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination." *Rouffet* at 1459. The court has also stated that actual evidence of a suggestion, or teaching, or motivation to combine is required and the showing of a suggestion, or teaching, or motivation to combine must be "clear and particular." *In re Dembiczak*, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

In view of the foregoing, the combined disclosures of Ebert and Ikeda do not render the claimed invention obvious. Accordingly, no *prima facie* case for obviousness exists. For these reasons, Applicant respectfully requests that the rejections be withdrawn.

#### Conclusion

Applicant respectfully submits that the pending claims are in condition for allowance, and notification to that effect is requested. The Examiner is invited to telephone Applicant's undersigned representative for any questions relating to this submission.

Respectfully submitted,

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